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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,861	10/20/2004	Yuko Matsumura	P25617	5143

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EXAMINER	
SZPIRA, JULIE ANN	

ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
10/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/500,861	MATSUMURA ET AL.	
	Examiner	Art Unit	
	JULIE A. SZPIRA	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7 and 10-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7 and 10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed 6/29/2010. Claims 1, 3-7 and 10-17 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 4-7 and 10-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Redding Jr. (US 2002/0156415)** in view of **Talish et al. (US 7,211,060)** further in view of **Hidaka et al. (US 4,990,340).**

Regarding claims 1, 4-7, 10-13, Redding Jr. discloses an ultrasonic percutaneous penetration device which, upon allowing a medicine containing an active ingredient to penetrate an organism from a skin surface (paragraph 68), allows vibration of ultrasonic waves to penetrate the organism from the skin surface, and can be used to whiten skin or reduce skin wrinkles, comprising:

an irradiation unit (60) that applies no less than two ultrasonic waves having different frequencies to skin or a surface capable of contacting the medicine, said irradiation unit including a first ultrasonic transducer (61) that generates ultrasonic waves at a first frequency and a second ultrasonic transducer that generates ultrasonic waves at a second frequency (61; Redding discloses that a plurality of transducers can be used within the irradiation unit) different from the first frequency (paragraphs 64 and 65); and a control unit (1) that controls irradiation conditions (such as frequency; paragraph 64) of the irradiation unit , said control unit controlling said first and second ultrasonic transducers to generate ultrasonic waves at said different frequencies simultaneously and serially (paragraphs 65 and 66), a massaging tool (patch, 2) for repeating pressing and releasing the portion of the subjected to penetration of medicine (where pulsed waves are transmitting through the patch the patch will press the medicament into the skin, and then release when the pulse is ended; paragraph 40) and discloses the active ingredient being a vitamin (paragraph 71) impregnated into a base material (paragraph 105; the drug is contained within a drug pocket of the transdermal patch) but fails to disclose the frequency being between 3 and 7 MHz and the specific active ingredients.

However, Talish et al. teaches a transdermal ultrasonic delivery system that functions at a frequency of 3 to 7 MHz (column 9, lines 9-11).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the device function at a frequency range of 3 to 7 MHz to allow for the desired site to be managed most effectively based on the suitability of the frequency for the treatment of the site.

Redding Jr. in view of Talish et al. discloses the invention substantially as claimed above, but fails to disclose the specific active ingredients to be used in conjunction with the transdermal irradiation device.

However, Hidaka et al. teaches a transdermal drug delivery device containing the active ingredient glutathione (column 6, lines 62-63; column 9, line 28), Vitamin A (column 9, line 1), capsaicin (column 7, line 31), and an antifungal agent (column 8, line 35).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use glutathione as the medicine as it has been proven to have the ability to transdermally transfer the medicine to the patient (Hidaka et al.; column 10, lines 17-20), and the use of an ultrasonic device would only increase the absorption of the drug.

4. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Redding Jr. (US 2002/0156415)** in view of **Talish et al. (US 7,211,060)** and **Hidaka et al. (US 4,990,340)** further in view of **Rowe et al. (US 6,234,990).**

Regarding claim 3, Redding Jr., Talish et al., and Hidaka et al. disclose the invention substantially as stated above, but fail to disclose a detection unit that detects the depth of a portion for penetration of the medicine, wherein the control unit controls the irradiation conditions so as to allow the medicine to penetrate to the depth detected by the detection unit.

However, Rowe et al. teaches a detection unit (sensor) that detects the depth of a portion for penetration of the medicine, wherein the control unit (controller, 90)

controls the irradiation conditions so as to allow the medicine to penetrate to the depth detected by the detection unit (column 12, lines 1-5 and 9-16).

It would have been obvious to one having ordinary skill in the art at the time in the invention was made to provide a depth sensor on the device to allow the medicine to penetrate to the correct depth (column 12, lines 10-12).

5. **Claims 14-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Redding Jr. (US 2002/0156415)** in view of **McDaniel (US 6,030,374)**

Regarding claims 14-17, Redding Jr. discloses a method of using an ultrasonic percutaneous penetration device in which simultaneously as or after a medicine containing an active ingredient is in contact with the skin, applying ultrasonic waves to a skin surface through the medicine (paragraphs 64 and 65), wherein applying ultrasonic waves comprises providing an irradiation unit (60) that applies no less than two ultrasonic waves having different frequencies to skin or a surface capable of contacting the medicine, said irradiation unit including a first ultrasonic transducer (61) that generates ultrasonic waves at a first frequency and a second ultrasonic transducer that generates ultrasonic waves at a second frequency (61; Redding discloses that a plurality of transducers can be used within the irradiation unit) different from the first frequency (paragraphs 64 and 65); providing a control unit (1) that controls irradiation conditions (such as frequency; paragraph 64) of the irradiation unit , said control unit controlling said first and second ultrasonic transducers to generate ultrasonic waves at said different frequencies simultaneously and serially in succession (paragraphs 65 and

66) and discloses the active ingredient being a vitamin (paragraph 71) but fails to disclose the device being used to lighten the skin or reduce wrinkles, the frequency being between 3 and 7 MHz and the specific active ingredients.

However, McDaniel teaches a method used to whiten skin (column 11, lines 31-40) or reduce wrinkles (column 12, lines 1-3), wherein the ultrasonic frequency applied is in the range of 3-7 MHz (column 7, lines 33-54) and the active ingredients applied are vitamin C or kojic acid (column 8, lines 13-27).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the device used for reducing wrinkles to function at a frequency range of 3 to 7 MHz to allow for the desired site to be managed most effectively based on the suitability of the frequency for the treatment of the site.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply vitamin C or kojic acid to the skin surface based on the inherent properties or qualities of the ingredients and their suitability for treating skin (column 8, lines 27-35).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Regarding claims 1, 3-7 and 10-13, in response to applicant's argument that the device of the present invention is used to lighten skin or reduce wrinkles, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant's arguments with respect to claims 14-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. S./
Examiner, Art Unit 3731
September 29, 2010

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
9/30/2010